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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/588,577 | 07/28/2008 | Peter Hamilton Kay | HYBRID-24324 WO.US | 8472 |
| 39843 | 7590 | 09/20/2011 | | |
| BELL & ASSOCIATES 58 West Portal Avenue No. 121 SAN FRANCISCO, CA 94127 | | | EXAMINER NOBLE, MARCIA STEPHENS | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 09/20/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

abell@bell-iplaw.com
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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/588,577 | Applicant(s) KAY, PETER HAMILTON | |
| | Examiner MARCIA S. NOBLE | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-29 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a method for identifying candidate genes capable of producing hybrid vigor in a plant comprising comparing the nucleotide sequence alleles of candidate genes from a plant which exhibits hybrid vigor with sequences from the corresponding alleles isolated from the parents of said plant; identifying nucleotide sequence differences in the alleles from said plant which exhibit hybrid vigor which codes for amino acid sequence variation; and identifying the amino acid sequence variation between alleles of the candidate gene in said plant is encoded by nucleic acid sequences which are located within two or more different exons with the candidate gene.

Group II, claim(s) 1-4 and 6-13, drawn to a method for identifying candidate genes capable of producing hybrid vigor in an animal comprising comparing the nucleotide sequence alleles of candidate genes from an animal which exhibits hybrid vigor with sequences from the corresponding alleles isolated from the parents of said animal; identifying nucleotide sequence differences in the alleles from said animal which exhibit hybrid vigor which codes for amino acid sequence variation; and identifying the amino acid sequence variation between alleles of the candidate gene in said animal is encoded by nucleic acid sequences which are located within two or more different exons with the candidate gene.

Group III, claim(s) 14-18, drawn to a method for identifying candidate genes capable of producing hybrid debility (HD) in a plant comprising comparing the nucleotide sequence alleles of candidate genes from a plant which exhibits HD with sequences from the corresponding alleles isolated from the parents of said plant; identifying nucleotide sequence differences in the alleles from said plant which exhibit HD which codes for amino acid sequence variation; and identifying the amino acid sequence variation between alleles of the candidate gene in said plant is encoded by nucleic acid

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sequences which are located within two or more different exons with the candidate gene.

Group IV, claim(s) 14-17, 19 and 20, drawn to a method for identifying candidate genes capable of producing HD in an animal comprising comparing the nucleotide sequence alleles of candidate genes from an animal which exhibits HD with sequences from the corresponding alleles isolated from the parents of said animal; identifying nucleotide sequence differences in the alleles from said animal which exhibit HD which codes for amino acid sequence variation; and identifying the amino acid sequence variation between alleles of the candidate gene in said animal is encoded by nucleic acid sequences which are located within two or more different exons with the candidate gene.

Group V, claim(s) 21, drawn to a method of producing hybrid vigor in a plant comprising comparing the nucleic acid sequence of alleles isolated from a gene from a plant which promotes hybrid vigor with a nucleic acid sequence from the corresponding alleles isolated from the parents of said plant; identifying nucleic acid sequence differences in the alleles from said plant which promote hybrid vigor which code for amino acid sequence variations; identifying the amino acid sequence variation between alleles of the nucleotide sequence in said plant is encoding by nucleotide sequences which are located within two or more different exons within the nucleic acid sequences; preparing a construct comprising nucleic acid sequences from the alleles which promote hybrid vigor which said plant; transforming said construct into a recipient plant cell; and regenerating the plant which expresses said construct from said plant cell.

Group VI, claim(s) 21, drawn to a method of producing hybrid vigor in an animal comprising comparing the nucleic acid sequence of alleles isolated from a gene from an animal which promotes hybrid vigor with a nucleic acid sequence from the corresponding alleles isolated from the parents of said animal; identifying nucleic acid sequence differences in the alleles from said animal which promote hybrid vigor which code for amino acid sequence variations; identifying the amino acid sequence variation between alleles of the nucleotide sequence in said animal is encoding by nucleotide sequences which are located within two or more different exons within the nucleic acid sequences; preparing a construct comprising nucleic acid sequences from the alleles which promote hybrid vigor which said animal; transforming said construct into a recipient animal cell; and regenerating the animal which expresses said construct from said animal cell.

Group VII, claim(s) 21, drawn to a method of producing HD in a plant comprising comparing the nucleic acid sequence of alleles isolated from a gene from a plant which promotes HD with a nucleic acid sequence from the corresponding alleles isolated from the parents of said plant; identifying nucleic acid sequence differences in the alleles from said plant which promote HD which code for amino acid sequence variations; identifying the amino acid sequence variation between alleles of the nucleotide

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sequence in said plant is encoding by nucleotide sequences which are located within two or more different exons within the nucleic acid sequences; preparing a construct comprising nucleic acid sequences from the alleles which promote HD which said plant; transforming said construct into a recipient plant cell; and regenerating the plant which expresses said construct from said plant cell.

Group VIII, claim(s) 21, drawn to a method of producing HD in an animal comprising comparing the nucleic acid sequence of alleles isolated from a gene from an animal which promotes HD with a nucleic acid sequence from the corresponding alleles isolated from the parents of said animal; identifying nucleic acid sequence differences in the alleles from said animal which promote HD which code for amino acid sequence variations; identifying the amino acid sequence variation between alleles of the nucleotide sequence in said animal is encoding by nucleotide sequences which are located within two or more different exons within the nucleic acid sequences; preparing a construct comprising nucleic acid sequences from the alleles which promote HD which said animal; transforming said construct into a recipient animal cell; and regenerating the animal which expresses said construct from said animal cell.

Group IX, claim(s) 22, drawn to a method of detecting the presence or absence of hybrid mRNA in a plant comprising isolating mRNA from a plant; comprising the mRNA to corresponding coding sequences of the plant's allele; and determining whether or not the mRNA sequence comprises nucleic acid sequences from two or more different exons.

Group X, claim(s) 22, drawn to a method of detecting the presence or absence of hybrid mRNA in an animal comprising isolating mRNA from an animal; comprising the mRNA to corresponding coding sequences of the animal's allele; and determining whether or not the mRNA sequence comprises nucleic acid sequences from two or more different exons.

Group XI, claim(s) 23-26, drawn to a method to overcome hybrid vigor in a plant comprising introducing a construct comprising exons from different alleles of a gene, wherein said exons code for amino acid variations found in only one allele, which that said construct does not contain a nucleic acid sequence that is the same as either allele and is capable of producing hybrid mRNA and said construct.

Group XII, claim(s) 23-26, drawn to a method to overcome hybrid vigor in an animal comprising introducing a construct comprising exons from different alleles of a gene, wherein said exons code for amino acid variations found in only one allele, which that said construct does not contain a nucleic acid sequence that is the same as either allele and is capable of producing hybrid mRNA and said construct.

Group XIII, claim(s) 23-26, drawn to a method to overcome HD in a plant comprising introducing a construct comprising exons from different alleles of a gene, wherein said

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exons code for amino acid variations found in only one allele, which that said construct does not contain a nucleic acid sequence that is the same as either allele and is capable of producing hybrid mRNA and said construct.

Group XIV, claim(s) 23-26, drawn to a method to overcome HD in an animal comprising introducing a construct comprising exons from different alleles of a gene, wherein said exons code for amino acid variations found in only one allele, which that said construct does not contain a nucleic acid sequence that is the same as either allele and is capable of producing hybrid mRNA and said construct.

Group XV, claim(s) 27-29, drawn to a method of making a transgenic non-human animal comprising inserting a synthetic gene into a non-human somatic cell or cell nucleus prior to transferring said somatic cell or cell nucleus, wherein said synthetic gene comprises exons from different alleles of a gene, wherein said alleles code for amino acid sequence variation, where the variation does not occur in the same allele.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

In the instant application, situation A applies:

Groups I, II, V, and VI have the special technical feature of candidate genes or genes capable of producing hybrid vigor. However, Groups III, IV, VII, and VIII do not have this special technical feature, but rather have the special technical feature of candidate genes or genes capable of producing hybrid vigor. Groups IX and X have a special technical feature of hybrid mRNA encoding alleles but do not have the special technical features of Groups I-VIII. Groups XI-XV have a special technical feature of introducing construct encoding genes comprising exons from different alleles but do not have the special technical features of groups I-X. As such, there is no one special technical feature that links all of the claims of the claim set. Therefore, the instant claim set lacks unity of invention.

In the instant situation, situation B applies:

The claims are drawn to multiple methods of use, multiple methods of making an allele or construct, and multiple products, such as a construct and a transgenic animal. Multiple products and multiple methods are not one of the special combinations of inventive entities deemed to have unity of invention. Thus, the claims lack unity of invention.

The following election of species is also required:

If Applicant elects a group drawn to a plant, Applicant is required to elect one species of plant as recited in claim 5. This election of species is being required because each of the species of plants, as recited in claim 5, are distinct plant species and a search of each of these plant species would require extensive amounts of searching, which would be considered a signification search burden.

If Applicant elects a group drawn to an animal, Applicant is required to elect one species of animal that falls within one particular order, one particular family, and one particular genus, As recited in claims 6-13. In other words, elect a particular species of animal and the order, family, and genus that correspond to the species of animal. This election of species is being required because each of the species of animals, orders, families, and genus, as recited in claim 6-13, are distinct species of animals and a search of each of these species would require extensive amounts of searching, which would be considered a signification search burden.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement,

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the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be

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Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

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requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCIA S NOBLE/
Primary Examiner, Art Unit 1632